



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 29, 2015

CareFusion
Ms. Joy Greidanus
Regulatory Affairs Manager
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K150523

Trade/Device Name: AVAmax Vertebral Balloon
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, NDN
Dated: September 17, 2015
Received: September 18, 2015

Dear Ms. Greidanus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved OMB No 0910-0120

Expiration Date January 31, 2017

See PRA Statement below

Indications for Use

510(k) Number (if known)
Unknown K150523

Device Name

AVAmx Vertebral Balloon

Indications for Use (Describe)

Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K150523

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

| SUBMITTER INFORMATION | |
|--|---|
| Name | CareFusion |
| Address | 75 North Fairway Drive, Vernon Hills IL 60061 USA |
| Phone number | (847) 362-8103 |
| Fax number | (312) 949-0583 |
| Establishment Registration Number | 1423507 |
| Name of contact person | Joy Greidanus |
| Date prepared | September 17, 2015 |
| NAME OF DEVICE | |
| Trade or proprietary name | AVAmax Vertebral Balloon |
| Common or usual name | Inflatable Bone Tamp |
| Classification name | Arthroscope |
| Classification panel | Orthopedic |
| Regulation | Class II per 21CFR §888.1100, Procode HRX Class II per 21CFR §888.3027, Procode NDN |
| Legally marketed device(s) to which equivalence is claimed | CareFusion Inflatable Bone Tamps, K131820 |
| Reason for 510(k) submission | Modifications to device; additional sizes and material. |
| Device description | The Inflatable Bone Tamp (IBT) was designed for use in balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture and preventing cement leakage, while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. |
| Intended use of the device | Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement). |

| SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE | | |
|--|-----------------------------------|--|
| Characteristic | New Device | Predicate 11G CareFusion Vertebral Balloon K131820 |
| Compatible cannula size | 11G, 13G | 11G |
| Balloon lengths | 10mm, 15mm, 20mm | 15mm, 20mm |
| Balloon inflation medium | 60% contrast recommended | 60% contrast recommended |
| Markers | Radiopaque | Radiopaque |
| Balloon shape | Cylindrical | Cylindrical |
| Maximum recommended inflation pressure | 400 psi (27 ATM) | 400 psi (27 ATM) |
| Maximum recommended inflation volume | 2-4 mL | 4-6 mL |
| PERFORMANCE DATA | | |
| SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE | | |
| Performance Test Summary-New Device | | |
| Characteristic | Standard/Test/FDA Guidance | Results Summary |
| Inflation pressure | Constrained burst test | The balloon catheters exceeded the requirements for the minimum burst pressure in a constrained environment |
| Inflation volume | Unconstrained burst test | The balloon catheters exceeded the requirements for the minimum burst volume in an unconstrained environment |
| Balloon double wall thickness | Calibrated measurement | The double wall thickness of the balloons was substantially equivalent to that of the predicate devices |
| Simulated Use | Cadaver | Cadaveric simulated use testing demonstrated substantial equivalence in performance. |
| SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION | | |
| N/A – No clinical tests were conducted for this submission | | |
| CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA | | |
| The results of the non-clinical tests show that the CareFusion balloon catheters meet or exceed all performance requirements, and are substantially equivalent to the predicate devices. | | |